Clinical trials of drugs

1919. SHRI KHAN GHUFRAN ZAHIDI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the details of the new drug applications received during 2002;

(b) the number of the drugs for which clinical trials are being done alongwith the names of the Drugs, Companies and the Centre approved for the trial; and

(c) in which manner DCGI monitor the authenticity of such trials?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRIMATI SUSHMA SWARAJ): (a) During the year 2002, 1017 applications of various categories were received in the office of DCG(I) which includes application for New Unapproved Drugs (NDA)-189, Investigational New Drug applications (IND)-05 and remaining 823 applications for categories like subsequent New Drug applications (SNDA), New Bulk Drug, Fixed Dose Combination, Recombinant products, New Indications and New Dosage form etc.

(b) Information is being collected and will be laid on the table of the House.

(c) Clinical trial are required to be conducted by qualified clinical investigators as per Good Clinical Practice (GCP) guidelines and after due approval by Institutional Ethics Committee. The Ethics Committee are also required to follow "Ethical Guidelines for Biomedical Research on Human subjects" published by Indian Council of Medical Research.

Stock of medicines in CGHS

1920. SHRI MANOJ BHATTACHARYA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether under existing system of supply of medicine, the CGHS dispensaries are authorized to keep stock of two hundred eighty varieties of medicines only;

(b) whether it is a fact that any drug prescribed by specialists outside the aforesaid varieties has to be initially purchased by the beneficiary and subsequently claimed for reimbursement;